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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/401,839	09/22/1999	MAURICE KENT GATELY	1803-247	5191

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HOFFMANN-LA ROCHE INC.
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EXAMINER

MERTZ, PREMA MARIA

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 02/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/401,839

Applicant(s)

Gately et al.

Examiner

Prema Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 22, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-38 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. Claims 1-32 have been canceled previously. Claims 33-38 are under consideration.
2. Receipt of applicant's arguments filed in Paper No. 18 (10/22/01) is acknowledged.
3. Applicant's arguments filed in Paper No. 18 (10/22/01), have been fully considered but were non-persuasive. The issues are restated below.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102(e)

5. Claims 33-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Trinchieri et al. (US Patent No. 5,811,523).

This rejection is maintained for reasons of record set forth at page 5 of the previous Office action (Paper No. 5, 1/24/00) and on page 2 (Paper No. 15, 4/20/01).

Applicants argue that they have previously sought, pursuant to 37 C.F.R. §§ 1.607 and 1.608(a) to provoke an interference between the instant application and U.S. Patent No. 5,811,523. However, contrary to Applicants arguments, the request under 37 C.F.R. §§ 1.607 and 1.608(a) to provoke an interference has been considered but does not suffice to overcome the rejection of claims 33-38 under 35 U.S.C. 102(e) as being anticipated by Trinchieri et al. (US Patent No. 5,811,523). The crucial issue here is that the priority date for US Patent No. 5,811,523, is 11/10/1988, which is the earliest application that describes partial amino acid sequences of the protein and the biological activity of the protein, combined with the routine skill of one in the art at that time, a monoclonal

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antibody which reacts with the CMLF protein (also known as IL-12) was enabled and had utility (methods of diagnosis or therapeutic use). Therefore, an interference with U.S. Patent No. 5,811,523 and the instant application cannot be declared without a showing under 37 CFR 1.608(b), for compliance of which must be supplied a declaration or an affidavit to provoke an interference with the patent whose effective filing date antedates that of the instant application by more than 3 months.

In conclusion, since the specification of Trinchieri's earliest application 07/269,945 filed 11/10/88, does disclose a single credible, specific or substantial utility for the instant antibodies to the CLMF polypeptide, Applicants arguments with respect to why this earliest application fails to support enablement and/or utility of the subject matter of the count, are found to be non-persuasive.

Claim Rejections - 35 USC § 103

6. Claims 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trinchieri et al. (U.S. Patent No. 5,811, 523).

This rejection is maintained for reasons of record set forth at pages 3-4 of the previous Office action (Paper No. 5, 1/24/00) and on page 3 (Paper No. 15, 4/20/01) and for the reasons as set forth in paragraph 5 above.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
January 31, 2002